

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

CRIMINAL NO.
09-10330-GAO

UNITED STATES OF AMERICA

v.

STRYKER BIOTECH, LLC
MARK PHILIP, WILLIAM HEPPNER,
DAVID ARD, and JEFFREY WHITAKER

**ORDER ON DEFENDANTS'
JOINT MOTION FOR A BILL OF PARTICULARS**

July 21, 2010

DEIN, M.J.

I. INTRODUCTION

The defendants, Stryker Biotech, LLC (“Stryker Biotech”), its former President Mark Philip, and three of its current sales managers, William Heppner, David Ard and Jeffrey Whitaker, are charged in a sixteen-count Indictment in connection with the promotion and sale of Stryker Biotech’s medical device products OP-1 (a bone morphogenic protein that assists in bone growth) and Calstrux (a bone void filler). In particular, all of the defendants are charged with a wire fraud scheme in violation of 18 U.S.C. § 1343 (Counts I - V), and conspiracy to defraud the United States and to distribute a misbranded medical device in violation of 18 U.S.C. § 371 (Count VI). Defendants Stryker Biotech, Ard and Whitaker also are charged with distribution of a misbranded device under the Food, Drug and Cosmetics Act in violation of 21 U.S.C.

§§ 331(k), 333(a)(2) and 352(f) (Counts VII - XIV), and Stryker Biotech and Philip are charged with false statements in violation of 18 U.S.C. § 1001 arising out of the annual reporting to the FDA about OP-1 Putty (Counts XV and XVI). This matter is presently before the court on the Defendants' Joint Motion for a Bill of Particulars (Docket No. 54) "Motion"). While it is undisputed that the defendants have been provided with a full explanation of all of the specific incidents identified in the Indictment, as well as the identity of all individuals and entities referenced therein, the defendants, by their motion, are seeking considerably more details about the alleged fraudulent conduct and false statements charged in the Indictment. In addition, the individual defendants have requested further clarification of which paragraphs refer to them.

The Government has agreed to clarify whether any of the paragraphs which refer only to "Stryker Biotech" relate to conduct of the individual defendants. With that clarification, the Motion is DENIED. The defendants' objections, which are basically that the Indictment fails to state a claim of felony misconduct, are more appropriately raised in a motion to dismiss. As detailed below, this court finds that the Indictment and subsequent discovery provide sufficient information to allow the defendants to prepare an adequate defense.

II. STATEMENT OF FACTS

The Government alleges that the defendants engaged in a two-year conspiracy, from approximately February 2006 until at least February 2008, relating to the false and fraudulent promotion of OP-1 and Calstrux. (Indictment ¶¶ 60-61). In particular, but

without limitation, it is alleged that the defendants marketed Calstrux as a product to be mixed with OP-1 in order to increase the volume and improve the handling qualities of OP-1, with knowledge that the FDA had only approved bone fillers such as Calstrux “to fill voids in bones that resulted from bony defects or injury” and that such bone fillers “were not approved to be mixed with a bone morphogenic protein like OP-1.” (Id. ¶¶ 22-23). It is further alleged that Stryker Biotech sought FDA approval for Calstrux as a bone void filler product only, and never indicated that it intended Calstrux to be used in a mixture with OP-1. (Id. ¶¶ 23-24).

According to the Indictment, Philip, Heppner, Ard and Whitaker “each knew and understood that the FDA had not approved the mixture of OP-1 and Calstrux, that no clinical trial in humans had been conducted to determine whether the mixture of OP-1 and Calstrux was safe or effective, and that no adequate directions for use could be written for the mixture of OP-1 and Calstrux because the mixture was not FDA approved” yet they nevertheless promoted and marketed the mixture of OP-1 and Calstrux. (Id. ¶¶ 28, 29, 32, 44). Specifically, it is alleged that Stryker Biotech, Philip, Heppner, Ard and Whitaker “promoted or caused to be promoted to surgeons and surgical staff ‘recipes’ or mixing instructions on how to combine Calstrux and OP-1.” (Id. ¶ 32). Examples of such promotions are included in the Indictment, as are allegations regarding specific actions taken by the individual defendants in connection with such promotions. (See, e.g., id. ¶¶ 32, 49, 54, 63(g)(3)). Similarly, the Indictment describes the defendants’

involvement in a number of activities by which, the Government contends, the defendants furthered the alleged scheme and/or conspiracy. (See, e.g., id. ¶¶ 37, 53).

Significantly, the Government has provided the defendants with grand jury testimony and exhibits, as well as memoranda of interviews of a number of Stryker Biotech sales people. Such material was gathered in connection with the instant Indictment as well as in connection with the cases of four former Stryker Biotech employees who have entered into plea and cooperation agreements with the Government, and who pled guilty to charges of felony misbranding arising out of the promotion of a mixture of Calstrux and OP-1. This information, according to the Government, identifies the key witnesses in the action, the key exhibits, and the key events on which the Government intends to rely in the trial of this case, and provides the defendants with a “road map” of the Government’s case. (See Gov’t Opp. (Docket No. 59) at 3-4).

According to the Government, such early discovery also provides a road map of the false statements on which it intends to rely at trial. (See id. at 13). For example, it is alleged in the Indictment as follows:

It was a further part of the scheme and artifice to defraud that the Stryker Biotech sales force, including representatives of affiliated companies and distributors, misled surgeons and surgical staff regarding the mixture of OP-1 and Calstrux in a variety of different ways in different circumstances, including by one or more of the following: (a) failing to disclose that there were adverse events arising from a combined use of Calstrux and OP-1; (b) failing to disclose that the mixture of OP-1 and Calstrux was not FDA approved; (c) failing to disclose that the mixture of OP-1 and Calstrux had never been clinically studied in humans; (d) affirmatively misrepresenting the nature of the FDA “approval” by

referring to the HDE as a “steppingstone” to full approval, or telling surgeons that there was no difference between an HDE and a PMA in terms of the ability to use the product “off-label”; and (e) affirmatively misrepresenting the mixture of Calstrux and OP-1 was simply OP-1 when presented to the surgeon, and/or failing to disclose that the mixture of OP-1 and Calstrux was not simply OP-1 knowing that the surgeon so assumed.

(Indictment ¶ 48). More specific examples are identified in the Indictment. (See, e.g., id. ¶¶ 34, 36, 38-39, 44, 49, 50, 58, 63). In addition, the Government has represented that the discovery produced to date identifies the key exhibits, witnesses and events on which it relies to support its claims.

Finally, but again without limitation, the Indictment identifies various representations to the Government which the prosecution contends were false and which are at issue in this case. These include annual reports, test results and correspondence submitted to the FDA (id. ¶¶ 71-78), and statements made during an FDA inspection. (Id. ¶ 81).

Defendants now move pursuant to Fed. R. Crim. P. 7(f) for a bill of particulars, seeking further information as to every part of the Indictment in their 26-page request for information. (See Motion at Ex. A). In particular, the defendants are seeking, among other things, (1) the “specific identities of: (a) the persons to whom the indictment is referring in each instance that it uses generic terms” and (b) the specific individuals or entities “that were victims of this alleged conduct;” (2) “[t]he time, place, and substance of each fraudulent misrepresentation and/or omission regarding OP-1 and Calstrux that the Government will seek to prove was made by Stryker Biotech’s employees or agents;” including enough information “to enable the Defendants to understand what information

was required to be disclosed and why such omission allegedly constituted fraud” and “whether and on what basis the Government intends to hold the Defendants criminally responsible for the alleged acts of others”; (3) “[t]he acts of craft, trickery, deceit and dishonesty by which Defendants conspired to ‘defraud the FDA’ by ‘impairing, impeding, obstructing, and defeating’ the agency’s ‘lawful functions’” and (4) “[t]he time, place, and substance of Defendant Philip’s concealment by trick, scheme or device that Stryker Biotech was treating more than 4,000 patients per year with OP-1 Putty,” including the entities from whom such information was concealed “and the alleged nexus (if any) between the alleged deception and the function of any agency of the United States.” (Motion at 1-2). The defendants contend that they need this information to prepare an adequate defense to the crimes with which they are charged. Because this court finds that the Indictment and subsequent discovery provided by the Government adequately inform the defendants of the charges brought against them and provide sufficient information to allow the defendants to prepare an adequate defense, the motion is DENIED.

III. DISCUSSION

A. Legal Standard for Bills of Particulars

A bill of particulars is not a tool of discovery, and its purpose is not to obtain disclosure of evidence, witnesses to be offered at trial, or the government's legal theories. See United States v. Smith, 776 F.2d 1104, 1111 (3d Cir. 1985); United States v. Mannino, 480 F. Supp. 1182, 1185 (S.D.N.Y. 1979); see also United States v. Jones, 678

F. Supp. 1302, 1304 (S.D. Ohio 1988) (citing United States v. Kilrain, 566 F.2d 979 (5th Cir.), cert. denied, 439 U.S. 819, 99 S. Ct. 80, 58 L. Ed. 2d 109 (1978)). Rather, its purpose "is to provide the accused with detail of the charges against him where necessary to enable him to prepare his defense, to avoid surprise at trial, and to protect against double jeopardy." United States v. Paiva, 892 F.2d 148, 154 (1st Cir. 1989), and cases cited.

Whether—and to what extent—a bill of particulars should be granted is determined on the basis of the facts and circumstances presented in each case, and is within the discretion of the trial court. United States v. Leach, 427 F.2d 1107, 1110 (1st Cir. 1970), cert. denied, 400 U.S. 829, 91 S. Ct. 95, 27 L. Ed. 2d 59 (1970). When considering a defendant's request for a bill of particulars, a court may consider such factors as the complexity of the charges, the clarity of the indictment, and the discovery and other information available to the defendant. United States v. Walker, 922 F. Supp. 732, 739 (N.D.N.Y. 1996) (citing United States v. Diaz, 675 F. Supp. 1382, 1390 (E.D.N.Y. 1987)).

"[I]ndictments need not be infinitely specific," but need only "elucidate[] the elements of the crime, enlighten[] a defendant as to the nature of the charge against which she must defend, and enable[] her to plead double jeopardy in bar of future prosecutions for the same offense." United States v. Sepulveda, 15 F.3d 1161, 1192 (1st Cir. 1993), cert. denied, 512 U.S. 1223, 114 S. Ct. 2714, 129 L. Ed. 2d 840 (1994). Thus, motions for bills of particulars "need be granted only if the accused, in the absence of a more

detailed specification, will be disabled from preparing a defense, caught by unfair surprise at trial, or hampered in seeking the shelter of the Double Jeopardy Clause." Id. at 1192-93, and case cited.

Additionally, a defendant seeking particularization "has the burden of showing by brief, affidavit, or otherwise that nondisclosure would lead to prejudicial surprise or the obviation of opportunities for meaningful defense preparation." United States v. Rogers, 617 F. Supp. 1024, 1027 (D.Colo. 1985); see also Sepulveda, 15 F.3d at 1192-93. A defendant will not be prejudiced if "normal investigation [will] disclose[] the further information they require[]." Leach, 427 F.2d at 1110. Moreover, bills of particulars are unnecessary when the information sought is available from other sources. See, e.g., United States v. Bortnovsky, 820 F.2d 572, 574 (2d Cir. 1987) (noting that generally bills of particulars are inappropriate when the information sought is available "in the indictment or some acceptable alternate form"), and cases cited.

B. The "Roadmap" Eliminates the Need for Further Particulars

The defendants' requests for additional details must fail for two very basic reasons: either they are seeking legal theories which are beyond the scope of a bill of particulars, or the details have been provided both in the Indictment itself as well as in the grand jury testimony, exhibits and witness statements which have been produced. By identifying the key witnesses, key exhibits and key testimony on which it intends to rely at trial, the Government has undertaken the task of sifting through the thousands of pages of documents the defendants have produced. Thus, this is not a situation where the

defendants are being “forced to comb through [a] veritable mountain of documents and to attempt to guess which of the numerous transactions documented therein, and conducted over a [multi]-year period, are alleged by the government to have been improper.” United States v. Savin, No. 00CR.45 (RWS), 2001 WL 243533, at *3-4 (S.D.N.Y. Mar. 7, 2001). Moreover, the Government has provided the defendants with the results of its analyses through grand jury testimony, witness interviews, and selected exhibits. Accordingly, this is not a case, like those cited by the defendants, where the Government’s production of large amounts of documents increases, rather than obviates, the need for a bill of particulars. *See, e.g., Bortnovsky*, 820 F.2d at 574-75 (concluding bill of particulars was warranted where indictment charged defendants with twelve counts and Government produced 4,000 documents, leaving the defendants “unguided as to which documents would be proven falsified or which of some fifteen burglaries would be demonstrated to be staged”); United States v. Davidoff, 845 F.2d 1151, 1154-55 (2d Cir. 1988) (finding bill of particulars should have issued where Government produced approximately 6,000 documents and misled defendant charged with five counts as to the importance of many such documents). Rather, the defendants here have been adequately informed about the details of their alleged wrongdoing so as to be able to identify and defend against the crimes with which they are charged.

C. The Particular Claims

The Government has charged the defendants with a fraud scheme

in which defendants knew: (1) that a mixture of Calstrux and OP-1 had never been clinically tested; (2) that a mixture of Calstrux and OP-1 had never been approved by the FDA; (3) that patients receiving a mixture of Calstrux and OP-1 had suffered from adverse events; and (4) that defendants had taken a number of steps to promote that mixture, such as (a) training the sales force to do so; (b) providing advice about the recommended dryness of the mixture; (c) providing bundled discounts of OP-1 and Calstrux (as an extender).

(Gov't Mem. at 13) (citing Indictment ¶¶ 34, 36, 38, 44, 47, 49, 50). As detailed above, the Indictment provides specific examples of the allegedly fraudulent conduct in which the date, substance, and parties involved are identified. (E.g., Indictment ¶ 58).

Nevertheless, the defendants contend that they need more information about the alleged perpetrators and victims of the alleged fraudulent misrepresentation. (See Defs. Mem. (Docket No. 55) at 5-7). However, the Government has identified all individuals specifically named in the Indictment, and has provided through early discovery the key incidents on which it intends to rely. This is not a situation like that presented in United States v. Davidoff, 845 F.2d 1151(1988), on which the defendants rely. In Davidoff, the defendant was put on notice that he was “obliged to defend against extortionate schemes directed at one company,” but at trial was “confronted with evidence of extortions aimed at entirely different companies.” Id. at 1154. The defendants here do not face the same possibility of surprise. Between the “roadmap” and the Indictment, the defendants are aware of the key events at issue.

The defendants are also seeking “the substance, date, time, and place of each false statement or concealment and the persons involved,” claiming that the Indictment is too

general and uninformative. (Defs. Mem. at 8-9). Again, however, as described above the Indictment provides a number of specific examples of the fraud charged. (See, e.g., Indictment ¶¶ 48, 58, 63). The statements at issue have been clearly identified. The Government also has identified the key witnesses, their testimony and the key exhibits in support of the charges. “Given the degree of detail in the indictment and the government’s provision of searchable discovery databases and a list of its key documents, the defendants have not proven that they require more particularization to adequately prepare their defenses, avoid prejudicial surprise at trial, and protect against future double jeopardy.” United States v. Ferguson, 478 F. Supp. 2d 220, 227 (D. Conn. 2007).

The defendants are also seeking a myriad of details relating to the conspiracy charge.¹ Generally, however, “‘the defendant does not ‘need’ detailed evidence about the conspiracy in order to prepare for trial properly,’” and, therefore, defendants “are not entitled, by way of a bill of particulars, to details such as how and when a conspiracy was formed, as well as when each participant entered it.” United States v. Steele, 83 F. Supp. 2d 340, 342 (N.D.N.Y. 2000) (quoting United States v. Feola, 651 F. Supp. 1068, 1132 (S.D.N.Y. 1987)). “Moreover, a conspiracy does not normally occur at only one particular time or place; it often takes shape and is carried out over a period of time, frequently in various locales. A conspiracy may include several overt acts, but, as the government is not required to prove any of the particular acts constituting the conspiracy,

¹ The Government has identified any unindicted co-conspirators, so that part of the defendants’ request regarding the conspiracy charge has been withdrawn.

the absence of a statement of the precise dates and locations of such acts does not necessarily render the indictment impermissibly vague.” United States v. Hallock, 941 F.2d 36, 40-41 (1st Cir. 1991) (internal citation omitted). Here, the defendants have been provided with a wealth of information about the alleged wrongdoing in which they engaged. Any generalities have been refined through the identification of key witnesses and exhibits. Further details are not necessary in connection with the conspiracy claim.

Finally, there is no basis for further particulars regarding Philip’s actions. The Indictment addresses Philip’s alleged attempt to conceal information from the FDA. (See, e.g., Indictment ¶ 80). The identities of the individuals referenced in Count XVI have been provided to Philip. No further information is needed.

IV. CONCLUSION

For all the reasons detailed herein, the Defendants’ Joint Motion for a Bill of Particulars (Docket No. 54) is DENIED, subject to the Government’s agreement to clarify whether any of the paragraphs which refer only to “Stryker Biotech” relate to conduct of the individual defendants.

/ s / Judith Gail Dein
Judith Gail Dein
U.S. Magistrate Judge